Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. – 74. (Cancelled)

75. (Currently Amended) A method of producing a protein or a peptide in the urine of a non-human transgenic mammal, said method comprising:

(a) providing a non-human transgenic mammal having stably integrated into its genome an exogenous gene encoding a protein or a peptide comprising expression regulatory sequences operably linked to said exogenous gene encoding said protein or peptide; and

(b) allowing said exogenous gene encoding said protein or peptide to be expressed and to be secreted into the urine of said transgenic mammal,

wherein said expression regulatory sequences comprise 5' regulatory sequences, comprising a promoter, wherein said 5' regulatory sequences are selected from the group consisting of a 5' regulatory sequence of ~~an~~ **a** uromodulin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, ~~an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene~~ a uropontin/osteopontin gene and an aquaporin gene.

76. (Previously Presented) The method of claim 75, further comprising:

(c) collecting said urine containing said protein or peptide from said mammal; and

(d) separating said protein or peptide from said urine.

77. (Previously Presented) The method of claim 75, wherein said 5' regulatory sequence comprises a uromodulin promoter.

78. (Previously Presented) The method of claim 77, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

79. (Previously Presented) The method of claim 78, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

80. (Currently Amended) The method of claim 79, wherein said 3' regulatory sequences are selected from the group consisting of a 3' regulatory sequence of ~~an~~ **a** uromodulin gene, ~~an~~ **a** uroplakin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, ~~an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene~~ a uropontin/osteopontin gene and an aquaporin gene.

81. (Previously Presented) The method of claim 75, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

82. (Previously Presented) The method of claim 81, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

83. (Currently Amended) The method of claim 82, wherein said 3' regulatory sequences are selected from the group consisting of a 3' regulatory sequence of ~~an~~ **a** uromodulin gene, ~~an~~ **a** uroplakin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, ~~an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene~~ a uropontin/osteopontin gene and an aquaporin gene.

84. (Previously Presented) The method of claim 75, wherein said protein or peptide is an enzyme or an enzyme inhibitor.

85. (Previously Presented) The method of claim 84, wherein said enzyme is a protease, a glycosyltransferase, a phosphorylase, a kinase or a γ-carboxylase.

86. (Previously Presented) The method of claim 75, wherein said protein or peptide is selected from the group consisting of prothrombin, Factor VII, Factor IX, Protein C, Protein S, Factor V, Factor VIII, α1-anti-trypsin, antithrombin III, fibrinogen, albumin, an immunoglobulin, a hormone, a growth factor, erythropoietin, a bone morphogenetic protein and an ion channel protein.

87. (Previously Presented) The method of claim 75, wherein said transgenic mammal is a pig, sheep, goat, cow, rodent, rabbit or horse.

88. (Currently Amended) A non-human transgenic mammal that produces in its urine a protein or peptide, wherein said transgenic mammal has stably integrated into its genome an exogenous gene encoding a protein or peptide comprising expression regulatory sequences operably linked to said exogenous gene, wherein said expression regulatory sequences comprise 5' regulatory sequences, comprising a promoter, wherein said 5' regulatory sequences are selected from the group consisting of a 5' regulatory sequence of ~~an~~ **a** uromodulin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, ~~an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene~~ a uropontin/osteopontin gene and an aquaporin gene, and wherein said protein or peptide is detectable in the urine of said transgenic mammal.

89. (Previously Presented) The mammal of claim 88, further comprising:

(c) collecting said urine containing said protein or peptide from said mammal; and

(d) separating said protein or peptide from said urine.

90. (Previously Presented) The mammal of claim 88, wherein said 5' regulatory sequence comprises a uromodulin promoter.

91. (Previously Presented) The mammal of claim 90, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

92. (Previously Presented) The mammal of claim 91, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

93. (Currently Amended) The mammal of claim 92, wherein said 3' regulatory sequences are selected from the group consisting of a 3' regulatory sequence of ~~an~~ **a** uromodulin gene, ~~an~~ **a** uroplakin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, ~~an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene~~ a uropontin/osteopontin gene and an aquaporin gene.

94. (Previously Presented) The mammal of claim 88, wherein said expression regulatory sequences further comprise 3' regulatory sequences operably linked to said exogenous gene.

95. (Previously Presented) The mammal of claim 94, wherein said 3' regulatory sequences result in the expression of said exogenous gene in the urinary tract cells of the transgenic mammal.

96. (Currently Amended) The mammal of claim 95, wherein said 3' regulatory sequences are selected from the group consisting of a 3' regulatory sequence of ~~an~~ **a** uromodulin gene, ~~an~~ **a** uroplakin gene, a renin gene, an erythropoietin gene, an apolipoprotein E gene, ~~an osteopontin gene, an urinary kallikrein gene, an urinary thrombomodulin gene, an uropontin gene, a nephrocalcin gene~~ a uropontin/osteopontin gene and a aquaporin gene.

97. (Previously Presented) The mammal of claim 88, wherein said protein or peptide is an enzyme or an enzyme inhibitor.

98. (Previously Presented) The mammal of claim 97, wherein said enzyme is a protease, a glycosyltransferase, a phosphorylase, a kinase or a γ-carboxylase.

99. (Previously Presented) The mammal of claim 88, wherein said protein or peptide is selected from the group consisting of prothrombin, Factor VII, Factor IX, Protein C, Protein S, Factor V, Factor VIII, α1-anti-trypsin, antithrombin III, fibrinogen, albumin, an immunoglobulin, a hormone, a growth factor, erythropoietin, a bone morphogenetic protein and an ion channel protein.

100. (Previously Presented) The mammal of claim 88, wherein said transgenic animal is a pig, sheep, goat, cow, rodent, rabbit or horse.

101. (New) The method of claim 75, wherein said 5' regulatory sequence comprises a renin promoter.

102. (New) The method of claim 75, wherein said 5' regulatory sequence comprises a erythropoietin promoter.

103. (New) The method of claim 75, wherein said 5' regulatory sequence comprises an apolipoprotein E promoter.

104. (New) The method of claim 75, wherein said 5' regulatory sequence comprises a uropontin/osteopontin promoter.

105. (New) The method of claim 75, wherein said 5' regulatory sequence comprises an aquaporin promoter.

106. (New) The mammal of claim 88, wherein said 5' regulatory sequence comprises a renin promoter.

107. (New) The mammal of claim 88, wherein said 5' regulatory sequence comprises a erythropoietin promoter.

108. (New) The mammal of claim 88, wherein said 5' regulatory sequence comprises an apolipoprotein E promoter.

109. (New) The mammal of claim 88, wherein said 5' regulatory sequence comprises a uropontin/osteopontin promoter.

110. (New) The mammal of claim 75, wherein said 5' regulatory sequence comprises an aquaporin promoter.